

**Amendments to the Claims:**

This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

1. (Currently amended) An ~~oral~~-pharmaceutical formulation suitable for oral administration and in the form of ~~[[a]]~~ coated, flowable granules ~~granulate~~ in a sachet, wherein the coated granules ~~granulate~~ comprise~~[[s]]~~:
  - a pharmaceutically acceptable binder,
  - from 92 to 98% by weight of mesalazine or a pharmaceutically acceptable salt thereof,
  - wherein the coated granules, when suspended in an aqueous buffer at pH 7.5, release the mesalazine according to a release profile in which:~~and an amount of coating adjusted to the specific surface area of the granulate to provide the in vitro release characteristics of:~~
  - a) 5-25% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the granules ~~formulation~~ is released after 15 min;
  - b) 30-70% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the granules ~~formulation~~ is released after 90 min; and
  - c) 75-100% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the granules ~~formulation~~ is released after 240 min;when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.
- 2-5. (Canceled)
6. (Previously presented) The pharmaceutical formulation according to claim 1, having a similarity factor  $f_2$  above 30 as compared to a standard formulation having in vitro release characteristics such that

a) 12% of the total amount of mesalazine in the standard formulation is released after 15 min;

b) 50% of the total amount of mesalazine in the standard formulation is released after 90 min; and

c) 85% of the total amount of mesalazine in the standard formulation is released after 240 min;

when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.

7. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the pharmaceutically acceptable binder is an amount less than or equal to an amount selected from the group consisting of 1, 2, 3, 4, 5, 6, 7, and 8, 9, 10, and 12 % by weight.

8. (Canceled)

9. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the ratio of the weight of said coating to the weight of said mesalazine or said pharmaceutically acceptable salt thereof is selected from the group consisting of ~~0.1-10%, 0.3-7%, 0.5-5%, 0.7-3%, 0.8-2%, and 0.9-1.5%.~~

10. (Currently amended) The pharmaceutical formulation according to claim 1, consisting ~~essentially~~ of mesalazine, a pharmaceutically acceptable binder and a coating.

11. (Canceled)

12. (Withdrawn) A method for manufacturing an oral pharmaceutical formulation in the form of a granulate comprising more than 60% by weight of mesalazine or a pharmaceutically acceptable salt thereof, comprising:

a) mixing mesalazine or a pharmaceutically acceptable salt thereof with granulation liquid to form a mixture;

b) obtaining granulate by granulating, compacting or extruding the mixture;

c) drying the granulate;

d) optionally, adjusting the size of the granulate; and

e) optionally, sieving the granulate; characterized in the additional step of:

f) coating the granulate to form coated granulate; and optionally further:

g) sieving the coated granulate; and

h) air purging the coated granulate.

13. (Withdrawn) The method according to claim 12, wherein said coated granulate are packed in a sachet.

14. (Withdrawn) The method according to claim 12, wherein said granulation liquid consists of Povidone dissolved in water.

15. (Withdrawn) The method according to claim 12, wherein said drying step c) is performed in a fluid bed dryer.

16. (Withdrawn) The method according to claim 12, wherein said adjusting of size step d) is performed by milling.

17. (Withdrawn) The method according to claim 12, wherein said sieving step e) is performed by selecting granulate passing a 1.8 mm sieve, but not passing a 0.5 mm sieve.

18. (Withdrawn) The method according to claim 12, wherein said coating step f) is performed with ethylcellulose.

19. (Withdrawn) The method according to claim 12, wherein said coating step f) is performed by applying an amount of coating material adjusted, according to the specific surface area, to be in the range of 0.09 - 0.17 mg/cm<sup>2</sup> followed by drying.

20. (Withdrawn) The method according to claim 12, wherein said sieving step g) is performed on a rotation sieve.

21. (Previously presented) The pharmaceutical formulation according to claim 1, provided in a sachet comprising a total dosage amount of mesalazine or a pharmaceutically acceptable salt thereof selected from the group consisting of 0.5 g, 1.0 g, 1.5 g, 2 g, 3 g, 4 g, 5 g, 6 g, 8 g, and 10 g.

22. (Withdrawn) A method of treating intestinal bowel disease comprising administering to a patient in need thereof an oral pharmaceutical formulation in the form of a granulate comprising more than 60% by weight of mesalazine or a pharmaceutically acceptable salt thereof.

23. (Withdrawn) The method of claim 22, wherein said oral pharmaceutical formulation comprises an amount of mesalazine or pharmaceutically acceptable salt thereof selected from the group consisting of 0.5 g, 1.0 g, 1.5 g, 2 g, 3 g, 4 g, 5 g, 6 g, 8 g, and 10 g.

24. (Withdrawn) The method of claim 22, comprising administering said oral pharmaceutical formulation at a dosing schedule selected from the group consisting of 1, 2, 3, and 4 times per day.

25. (Withdrawn) The method of claim 22, wherein said intestinal bowel disease is selected from the group consisting of Crohn's Disease and Ulcerative Colitis.

26. (Previously presented) The pharmaceutical formulation according to claim 1, having in vitro release characteristics such that 40 - 60 % of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the formulation is released after 90 min, when measured in a model system using a USP Paddle System 2 operated at 37°C with stirring at 100 rpm.

27. (Previously presented) The pharmaceutical formulation according to claim 6, having a similarity factor  $f_2$  above 40 as compared to the standard formulation.

28. (Previously presented) The pharmaceutical formulation according to claim 6, having a similarity factor  $f_2$  above 50 as compared to the standard formulation.

29. (Previously presented) The pharmaceutical formulation according to claim 7, wherein the pharmaceutically acceptable binder comprises Povidone.

30. (Previously presented) The pharmaceutical formulation according to claim 1, wherein the coating comprises ethylcellulose.

31. (Withdrawn) The method according to claim 19, wherein said coating step f) is performed by applying an amount of coating material adjusted, according to the specific surface area, to be in the range 0.11 - 0.15 mg/cm<sup>2</sup>.

32. (Withdrawn) The method according to claim 20, wherein said sieving step g) is performed on a rotation sieve with a mesh size of 2.5 mm.

33. (Currently amended) An oral pharmaceutical formulation suitable for oral administration and in the form of [[a]] coated, flowable granules granulate comprising:  
92 to 98% by weight of mesalazine or a pharmaceutically acceptable salt thereof; [[and]]  
2 to 8% by weight of polyvinylpyrrolidone; and

~~wherein the formulation further comprises~~ a coating comprising a release modifying agent; ~~and is packed~~

the coated, flowable granules being in a sachet, capsule or blister package.

34. (New) The formulation of claim 33, comprising 4 to 6% by weight of polyvinylpyrrolidone.

35. (New) The formulation of claim 33, wherein the ratio of the weight of said coating to the weight of said mesalazine or said pharmaceutically acceptable salt thereof is selected from the group consisting of 0.7-3%.

36. (New) The formulation of claim 35, wherein the coating comprises ethylcellulose.